NEW YORK
LONDON
SINGAPORE
PHILADELPHIA
CHICAGO
WASHINGTON, DC
SAN FRANCISCO
SILICON VALLEY
SAN DIEGO
LOS ANGELES
TAIWAN
BOSTON
HOUSTON
AUSTIN
HANOI
HO CHI MINH CITY

DuaneMorris®

FIRM and AFFILIATE OFFICES

SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

www.duanemorris.com

SHANGHAI
ATLANTA
BALTIMORE
WILMINGTON
MIAMI
BOCA RATON
PITTSBURGH
NEWARK
LAS VEGAS
CHERRY HILL
LAKE TAHOE
MYANMAR
OMAN
A GCC REPRESENTATIVE OFFICE OF DUANE MORRIS

ALLIANCES IN MEXICO
AND SRI LANKA

October 13, 2020

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on October 14.

1. Rule 34 Discovery of Economic Loss Class Representatives

The Court-approved Plaintiff Fact Sheets ("PFS") for consumer class representatives and third-party payors ("TPPs") (collectively, the "PCRs") contained a handful of document requests limited in scope to certain issues that are essential to the PCRs' claims that they paid for valsartan-containing drugs ("VCDs"). They do not cover all of the issues pertinent to the class certification requirements under FRCP 23, especially the requirements to demonstrate a readily ascertainable class and to present a reliable model for establishing damages on a class-wide basis, but instead are the functional equivalent of the requests for "core" discovery to which the Manufacturer Defendants were required to respond. Just as Plaintiffs were entitled to do with respect to their core discovery requests, Defendants seek to supplement the PFS requests with document requests

under FRCP 34 that are necessary to elicit the information that is essential to the PCRs' obligations under Rule 23.[1]

In contrast to the more than ***140*** Rule 34 requests Plaintiffs were permitted to serve on Defendants, Defendants have proposed the PCRs respond to a handful of requests that do not duplicate the PFS requests and focus on the types of documents that go to the heart of the PCRs' class action allegations,[2] as follows:

Consumer Representative Requests	TPP Representative Requests
Warranties: Documents reflecting any express warranty you claim any defendant breached. ***Notices***: Communications giving notice to any defendant that it breached a warranty. ***Insurance***: Your insurance policies, summaries of benefits, summary plan descriptions, formularies or preferred drug lists, subscriber certificates, and descriptions or schedules of copayments for all plans that paid or reimbursed for VCDs during the relevant time period. ***Deductibles***: Documents showing that you met your annual "out-of-pocket" maximum or health benefit deductible for any year during the relevant time period. ***Physical Injury***: If you are claiming any bodily injury or damage to property, documents relating to such damages. ***Diminished Effectiveness***: If you are claiming diminished effectiveness of your VCDs, documents relating to such damages.	***Insurance Plans***: The Plan Documents, Summary Plan Descriptions, Group Insurance Policies, and Summaries of Benefits for all plans which serve as a basis for any damages you are claiming. ***Pharmacy Benefits Management and Plan Administration Agreements***: All contracts or agreements between you (or any assignor) and any PBM or plan administrator regarding how pharmacy benefits would be administered or paid out under any plan. This request excludes the Summacare and Emblem agreements previously produced. ***Transaction Prices***: Documents reflecting the gross price you (or an assignor) paid to cover the costs of VCDs or alternative blood pressure medications, and any related discounts, rebates, or fees you (or an assignor) received or paid. ***Insured Records***: For every insured person who obtained VCDs under any plan or policy serving as a basis for any damages you are claiming, that person's plan, policy, summary of benefits, summary plan description, and

[1] *See* ECF 582 (attaching Defendants' Rule 34 requests to be served on putative class representatives). "[D]efendant[s] [are] entitled to utilize … discovery devices to demonstrate that the facts cut against certification." 3 Newberg on Class Actions § 7:14 (2020).

[2] *See* Email from Goldberg to Slater, 10/8/20, attached as Ex. A.

Class Certification: To the extent not otherwise produced, all documents you contend support your "Class Action Allegations" (ECF 398, ELMC ¶¶ 422-434). ***Disclosure of Financial Interests***: Any agreement or communication between you and any other person relating to your (or their) financial interest in this case, including any indemnification or litigation finance agreements. ***Damages***: Documents that reflect your alleged out of pocket damages, the amount of any alleged diminution in value of the VCDs, and/or the value of the loss of benefit of any alleged bargain you claim to have made with any defendant regarding the VCDs.[3]	group insurance policy (as applicable), and documents showing what the insured actually paid for VCDs or other blood pressure medications. ***Formularies***: All formularies and preferred drug lists for each of your assignors not previously produced, and all documents reflecting how you (or any assignor) determined whether, or where, any VCDs or other blood pressure medications would appear on any formulary. ***Payment Terms***: The payment or co-payment terms applicable to each tier of the formulary/preferred drug list for all insureds on any plan or group insurance policy serving as the basis for any damages you are claiming. ***Safety Assessments***: Evaluations or statements regarding the safety or purity of any VCDs undertaken or obtained by you or any assignor. ***Alternatives***: Documents discussing alternative medications that you or your assignors could provide coverage for in lieu of VCDs. ***Warranties***: Documents reflecting any express warranty you claim any defendant breached. ***Notices***: Communications giving notice to any defendant that it breached a warranty.

[3] Just as the Defendants have been required to compile spreadsheets containing sales information, such as volumes sold, dates of sale, price per sale, and purchaser identities, the putative class representatives—especially the putative TPP class representatives, who purport to assert the claims of an undisclosed number of ERISA plans which allegedly purchased Defendants' VCDs in prescription drug coverage for their members—should be required to compile a spreadsheet setting forth their damages-related information, to the extent such spreadsheets have not already been compiled and produced to Defendants.

	Damages: Documents that reflect your alleged out of pocket damages, the amount of any alleged diminution in value of the VCDs, and/or the value of the loss of benefit of any alleged bargain you claim to have made with any defendant regarding the VCDs.

Given the juxtaposition between the conclusory "class action allegations" in the PCRs' master complaint, *see* ECF 398 at ELMC ¶¶ 422-434, and their patently overbroad alleged classes, on the one hand, and the rigorous analysis required under Rule 23, including the heightened standard for establishing ascertainability set by the Third Circuit in *Carrera v. Bayer Corp.*, 727 F.3d 300, 308 (3rd Cir. 2013) (method for identifying class members must be "reliable and administratively feasible"), on the other hand, Defendants proposed that the parties discuss the following questions during their recent Court-ordered meet and confer regarding Defendants' proposed Rule 34 requests in order to determine if any of the requests should be eliminated or modified.[4]

1. Have you produced all documents that you believe support class certification under Rule 23? Were all such documents produced in response to the Plaintiff Fact Sheets ("PFSs")?

2. Do you anticipate relying on preferred drug lists/formularies and/or co-pay information in moving for class certification? Have you obtained and reviewed any formularies, summary plan descriptions, plan documents, or group insurance policies applicable to any consumer class or TPP class representative? If so, when can these documents be produced?

3. Do you anticipate relying on drug replacement information in moving for class certification? Do you have any documents relating to replacement drugs that can be produced?

4. So that we may focus our discovery, how do you contend damages should be calculated for the causes of action in the economic loss action?

5. Have you produced all documents MSP has received from its Assignors?

6. Is MSP going to rely on the claims of its Assignors for purposes of satisfying Rule 23's certification requirements or at trial?

[4] *See* Email from Goldberg to Slater, 10/6/20, attached as Ex. B.

7. Are any consumer class representatives claiming that their VCDs were ineffective or less effective as a result of the presence of nitrosamines? If so, what documents do they intend to rely upon on that point, and when can those documents be produced?

8. Have you produced all documents that you believe identify unnamed class members of the consumer and TPP classes? Will you be providing identifying information for unnamed class members outside of subscriber IDs?

The PCRs stonewalled, refusing to respond to any of these questions, and refusing to provide any insight into their class action theories, other than what is pleaded in their economic loss master complaint, or into their damages theory or proposed damages calculation, other than that they demand 100% recovery of all amounts paid for Defendants' VCDs, *even if they did not contain nitrosamines*, since 2012. However, there is no question that Defendants need the above information to address the PCRs' eventual class certification motion, as this information goes directly to the questions whether the PCRs can demonstrate a readily ascertainable class,[5] and whether "individualized damages calculations … overwhelm questions common to the class." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 260 (3d Cir. 2016) (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013)).[6]

Based on the PCRs' anticipated theory of 100% recovery for all amounts paid for any of Defendants' VCDs, it is essential that Defendants be able to determine whether and the extent to which any putative class member, including the undisclosed number of assignors (who insured an undisclosed number of consumers) represented by the TPPs, actually paid for an allegedly impure VCD. Likewise, determining the offset attributable to the replacement drugs that each consumer (or each TPP assignor) would have purchased "but for" the alleged contamination of Defendants' VCDs will pose overwhelmingly individualized questions including, *inter alia*: what drug(s) would be prescribed; their cost(s); their placement(s) on their insurers' formularies; each individual PCR's co-pay and "out-of-pocket" maximum for every health plan that insured him/her;

---

[5] "To satisfy ascertainability as it relates to proof of class membership, the plaintiff must demonstrate his purported method for ascertaining class members is reliable and administratively feasible, and permits a defendant to challenge the evidence used to prove class membership." *Carrera*, 727 F.3d at 308; *see also Afzal v. BMW of N. Am., LLC*, No. 15-8009, 2020 WL 2786926, at *8-10 (D.N.J. May 29, 2020) (applying *Carrera*'s heightened ascertainability standard in denying certification of class of automobile purchasers) (attached hereto as Ex. C).

[6] "[A]n individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing or the issue is susceptible to generalized, class-wide proof." *Id*. (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016)).

and the actual costs each insurer or plan paid (factoring in rebates and credits arranged by any pharmacy benefits managers retained by the insurers/plans).

During last week's meet and confer the PCRs did not object to any of the above requests as seeking information irrelevant to their claims or obligations under Rule 23, nor did they contend that any seek information not within their possession, or that is unduly burdensome to collect.[7] Rather, they argued only that the requests are duplicative of the PFS requests, or that the PCRs have executed "authorizations" so Defendants can go subpoena the information from the PCRs' insurers or assignors.

Defendants disagree that the above requests are duplicative of the PFS requests. Regardless, the PCRs must be required to certify that they searched for the information sought above, and produced any such information that is within their possession. As for the PCRs' authorization shell game, the PCRs—who are parties to this litigation, who assert claims against Defendants, and who are forcing Defendants to bear the expense of discovery—should not be able to avoid their own collection and review of documents at the core of their Rule 23 claims by providing authorizations to Defendants and forcing them to undertake the additional burden of subpoenaing third parties for information the PCRs should have already collected and reviewed in connection with filing their claims. *See* Fed. R. Civ. P. 34 (party to case must produce items "in the responding party's possession, custody, or control"); *Hernandez v. Results Staffing, Inc.*, 907 F.3d 354, 361 (5th Cir. 2018) (holding plaintiff must produce responsive documents in his possession even if he has provided an authorization for the release of the same documents); *Doe v. Dist. of Columbia*, 231 F.R.D. 27, 35 (D.D.C. 2005) ("As to medical records, I expect them to be produced by plaintiff if he has a copy. Also, I consider medical records to be within plaintiff's control and expect that he will authorize their release to defendant …."). Plaintiffs would have scoffed at any Defendant who sought to skirt producing information in its possession because some of it was *also* in the possession of a third-party.

As the Court has frequently said, Plaintiffs must have "skin in the game" too, and with the parties on the brink of depositions of the PCRs at Plaintiffs' strenuous urging, now is the time for them to finally provide the discovery at the core of the most basic elements of their claims and Rule 23 allegations, not attempt to avoid that obligation, and, most certainly, not to assert, as Plaintiffs' did during last week's meet and confer, "you'll see our evidence when we file our motion for class certification." The Court should order the PCRs to search for and produce information in their possession responsive to Defendants' Rule 34 requests and to certify that they have done so.

---

[7] Any burden on the PCRs in responding to the handful of Rule 34 requests Defendants have proposed would be trivial compared to the millions of dollars and thousands of hours Defendants are being forced to expend responding to Plaintiffs' more than 140 Rule 34 requests, which were in addition to Plaintiffs' core discovery requests.

2. The Dates for Putative Class Representative Depositions Should Be Extended So That the Defendant Fact Sheet Process Can be Substantially Completed and Necessary Interests Can be Represented at the Depositions

The Court's October 2, 2020 Order requires that depositions of the purported class action plaintiffs begin between December 1, 2020 and January 15, 2021, and be completed by March 26, 2021. *See* ECF 585 ¶ 5. Defendants request that this period be adjusted to account for the ongoing Defendant Fact Sheet ("DFS") process so that the appropriate Defendants can be identified and attend the depositions to protect their interests.

The DFS process is designed, among other things, to attempt to identify which defendants up the supply chain were involved in the manufacture and sale of the valsartan-containing drugs consumed by each particular plaintiff by asking each link in the chain to attempt to identify from whom they purchased the at-issue product. This culminates with the API manufacturers, who obviously have a crucial stake in the case. The API manufacturers must know whether their API is at-issue for each putative class representative, and have the opportunity to attend each such deposition to protect their interests.

The four-phase DFS process began in mid-August: (1) the pharmacy defendants have 60 days to complete their DFS (mid-October), which triggers (2) the wholesalers/repackager defendants' 60 days to complete their DFS (mid-December), which triggers (3) the finished dose manufacturer defendants' 60 days to complete their DFS (mid-February), which triggers (4) the API manufacturer defendants' 60 days to complete their DFS (mid-April). (Dkt. 546) (order approving fact sheets for four levels with 60-day triggers).

Therefore, the earliest possible date that the DFS process could be completed for any putative class representative is mid-April, 2021. However, to this day not all of the purported class representatives have substantially completed their Plaintiff Fact Sheets, and their DFS process accordingly will lag behind. One putative class representative did not file any Plaintiff Fact Sheet at all (let alone a substantially complete one) until October 6, 2020, which makes the earliest possible date for the completion of the DFS process for that plaintiff June of 2021.

Defendants, however, are cognizant of the need for the case to move forward. For cases that involve only vertically integrated manufacturers (manufacturers whose finished dose uses only the API from a related company) all of the proper defendants will at least have the chance to be identified at the time the finished dose manufacturer DFS is complete (mid-February at the earliest). However, for finished dose manufacturers who use API from unrelated companies, all proper defendants for a particular putative class representative will not be identified until the entire DFS process is complete (mid-April at the earliest).

The Defendants therefore request that the dates for class representative plaintiffs be extended to begin February 15, 2021 and end August 31, 2021. This takes into account the need for all proper defendants to be identified while moving the deposition process ahead of the DFS process where possible.

3. Hearing on Defendants' Rule 12 Motion

Briefing under Rule 12 will be complete as of October 16, 2020, subject to Defendants' request to brief jurisdictional issues. Defendants request the Court set a date for oral argument on their Rule 12 motions, and advise as to whether the Court will be conducting that argument in person or via video conference in light of COVID-19 so the parties can plan accordingly.

4. Manufacturer Defendant Depositions

On October 7, 2020, Plaintiffs supplemented their original lists of proposed deponents. Per the Court's directive, the Manufacturer Defendants have reached out to Plaintiffs to meet and confer with them about those lists in order to address, among other things, the issues previously raised with the Court concerning the challenges posed by deposing foreign nationals and COVID-19.

5. Pace of Document Productions

The Court set a series of rolling production deadlines on April 15, 2020. *See* Hr'g Tr., Apr. 15, 2020, at 29:13-19. On the same day, at Plaintiffs' request, the Court ordered that Plaintiffs prioritize the documents they request to be produced earliest and ordered that "Defendants shall use good-faith, reasonable efforts to comply with plaintiffs' prioritization." *See id.* at 29:22-23. On May 7, 2020, Plaintiffs provided their proposed prioritization. During virtually every teleconference with the Court since the establishment of this process for Defendants' production, Plaintiffs have requested the Court make rulings to either speed up their productions or change their prioritization.[8] However, those requests have generally rung hollow because, with the exception of two issues that have been resolved between the parties, Plaintiffs have not complained about any specific deficiencies of any Defendants' productions either to the Court, or to any of the Defendants. Thus, the Court has reaffirmed its requirement that Defendants make good faith efforts in prioritizing their productions, and the Court has accepted Defendants' representations that they have done so. *See, e.g.*, ECF 564, Order, Aug. 26, 2020 ("Defendants shall continue to use reasonable good faith efforts to prioritize their document productions according to plaintiffs' requests."); Hr'g Tr., Sept. 16, 2020, at 9:21-22 ("If counsel made that representation, well, it's going to be accepted . . . .").

[8] For example, despite being actively and amicably engaged in ongoing discussions with ZHP's counsel regarding the scope of testing records to be produced by ZHP, Plaintiffs complained to the Court at the August 26, 2020 conference that Defendants still had not produced all testing records, and the Court entered a new deadline for certain testing records. *See* ECF 564, Order, Aug. 26, 2020. In addition, at the case management conference in mid-September, Plaintiffs complained to the Court, without having first met and conferred with the ZHP Parties, that they have not received all documents relating to a subset of documents they prioritized within the documents of certain priority custodians. *See, e.g.*, Hr'g Tr., Sept. 16, 2020, at 4:17-5:8.

As with previous teleconferences since the Court set the production schedule, Plaintiffs have not identified any specific issues regarding any aspect of any Defendants' production that Plaintiffs were unable to resolve and thus are ripe for resolution by the Court. Thus, there is no basis for the Court to make any changes to the process that was established six months ago, that has been progressing without a hitch since, and that is only approximately six weeks from completion. Rather than disrupt that process, the Court should allow Defendants to focus their resources on completing the task that has been at hand, and in which they have invested in good faith, since mid-April.

6. Privilege Logs

On August 28, 2020, the Court ordered that "[a]ll parties shall affirmatively indicate with their rolling productions of documents whether any responsive documents are being withheld on the grounds of privilege or work-product." Defendants have been complying with that Order. Like the above issue regarding the pace of Defendants' document productions, Defendants are not aware of any concerns Plaintiffs have related to privilege logs, and Plaintiffs have not satisfied their meet and confer obligations with such issues, if any.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Sarah Johnston, Esq. (*via email*)
Jeffrey Geoppinger, Esq. (*via email*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)